

DETAILED ACTION

It is noted that the foreign priority claim has been perfected. Therefore, the effective filing date of this application is 12/19/2003, the filing date of the Japanese priority document.

In the translation of the Japanese document at page 4, it is disclosed that polyarteritis nodosa is an example of vasculitis, as is aortitis syndrome. Aortitis syndrome is disclosed as being synonymous with Takayasu's arthritis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29, 31, 38, 39 and 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al., U.S. Patent Number 7,320,792 (effective filing date at least 7/20/1990) in view of Hirohata et al., Clinical Immunology and Immunopathology 66:225, 1993 (previously of record), and Noris et al., (Circulation 100:55-60, 1999)

Ito et al., U.S. Patent Number 7,320,792, published 5/2/2002, teach monoclonal antibody PM-1, an antibody against IL-6 receptor, and humanized forms thereof, for use in treatment of psoriasis, which is disclosed to be associated with elevated IL-6 levels; see claims 1-3.

Hirohata et al. teach that polyarteritis nodosa is associated with marked elevation of CSF IL-6 activity in parallel with CNS disease activity, and showed elevation of serum IL-6 in association with systemic systems.

Noris et al. (Circulation 100:55-60, 1999) teach that elevated IL-6 levels are associated with Takayasu arthritis, and consider such as indirect evidence that vasculitic lesions that characterize Takayasu arthritis are dependent on IL-6 producing cells; see page 57 and first paragraph of page 58. They refer again to a close correlation between IL-6 and the disease in the final paragraph of the paper.

Accordingly, in view of Ito's teaching that antibody PM-1 or humanized forms thereof are useful in the treatment of psoriasis, which is associated with elevated IL-6 levels, the person of ordinary skill in the art would be motivated to use Ito's antibodies to treat vasculitis or Takayasu arthritis, and would have had a reasonable expectation of success in view of the teachings of Hirohata and Norris that both polyarteritis nodosa and Takayasu arthritis are closely associated with elevated IL-6 levels.

Accordingly, the invention as claimed is *prima facie* obvious.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached

Monday from 8:00 A.M. to 4:30 P.M., and Tuesday, Thursday and Friday, 8:00 A.M. to 2:00 P.M. at telephone number 571-272-0893.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Jeffrey Stucker, at telephone number 571-272-0911.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to **571-273-8300**. Faxed draft or informal communications with the examiner should be directed to **571-273-0893**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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